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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,573	08/04/2000	Wilson T. Asfora	00-0050	2575

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EXAMINER

MAYNARD, JENNIFER J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

09/633,573

Applicant(s)

ASFORA, WILSON T.

Examiner

Jennifer J Maynard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 13-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 3. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 contains the trademark/trade name Jackson-Pratt. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a negative pressure bulb and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US 5,579,774 A).

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Miller et al. discloses a subdural evacuating port device/subarachnoid bolt (11) comprising a tubular portion for partial insertion into an opening in a skull (33, 35) of a patient, the tubular portion having proximal and distal ends and a lumen extending therebetween, see Column 8, lines 41-55, and a pair of medially-located wings (i.e. winged handles) for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion, see Figure 1 and Column 8, lines 60-63; the exterior surface at the proximal end of the tubular portion has self-tapping threads formed thereon adapted for cutting threads into the opening in the skull of the patient; the exterior surface at the distal end of the tubular portion has a plurality of annular barbs formed thereon for retaining an end of a conduit thereon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Knute et al. (US 4,903,707 A).

Miller et al. discloses the kit for evacuating a collection of fluid from a subdural space with the exception of a drill bit for forming an opening, a stop collar selectively lockable in a position on the drill bit for setting a maximum penetration of the drill into a surface, and a

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conduit having first and second ends, the first end adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative source.

Knute et al. discloses a kit for mounting a ventricular catheter assembly comprising a drill bit (81), a stop collar (83) and a conduit (19).

It would have been obvious to one having ordinary skill in the art to have modified the kit disclosed by Miller et al. with the drill bit, stop collar and conduit taught by Knute et al., so as to provide means for penetrating the skull of a patient for subsequent placement of the evacuating port device, to limit penetration of the drill bit thus preventing trauma to brain tissue adjacent the skull, and to provide means for draining fluid causing high intracranial pressure.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Lake (US 3,766,910 A).

Miller et al. discloses the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified Miller et al.'s kit for evacuating fluid from a subdural space by incorporating a retractor such as that

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which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Baudino (US 6,110,155 A).

Miller et al. discloses the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified Miller et al.'s kit for evacuating fluid from a subdural space by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Baudino (US 6,110,155 A), as applied to Claim 11 above, and further in view of McNeil et al. (US 4,828,546 A).

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Miller et al. in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified Miller et al.'s kit for evacuating fluid from a subdural space by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on 10:30 am-8:30 pm; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard
August 30, 2002



BRIAN L. CASLER
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